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RADER, FISHMAN & GRAUER PLLC
39533 WOODWARD AVENUE
SUITE 140
BLOOMFIELD HILLS, MI 48304-0610

EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,727	MARK, JOSEPH L.	
	Examiner	Art Unit	
	JEFFREY G. HOEKSTRA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/24/2009 has been entered.

Notice of Amendment

2. In response to the amendment filed on 08/24/2009, amended claim(s) 1 and 14 is/are acknowledged. The current rejections of the claim(s) 1-30 is/are *withdrawn*. The following new grounds of rejection are set forth:

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: at least first and second check valve elements 62 and 64 in Figures 6-10 as disclosed in paragraph 34.

4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claim 1 is objected to because of the following informalities: the three positive recitations of "inlet" in lines 8 and 10 should apparently each read "input". Appropriate correction is required.

6. Claim 13 is objected to because of the following informalities: the positive recitation of "leur" in line 2 should apparently read "luer". Appropriate correction is required.

7. Claim 14 is objected to because of the following informalities: the two positive recitations of "inlet" in lines 5 and 7 should apparently each read "input". Appropriate correction is required.

8. Claim 27 is objected to because of the following informalities: the positive recitation of "second input port" in line 4 should apparently read "said second input port". Appropriate correction is required.

9. Claim 27 is objected to because of the following informalities: the positive recitation of "said input port" in line 7 should apparently read "said second input port". Appropriate correction is required.

10. Claim 29 is objected to because of the following informalities: the positive recitation of "second input port" in line 4 should apparently read "said second input port". Appropriate correction is required.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 3, 4, 6, 8, 9, 14, 16, 17, 18, 19, 21, 22, and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Siegmund (US 4,598,698).

13. For independent claim 1, Siegmund discloses a biopsy system (the vacuum assisted retrieval instrument/ retrieval mechanism/ biopsy forcep inserted through channel 26 as positively recited in column 1 lines 9-21, column 2 lines 41-46 and 50-52, and column 4 lines 1-4) (as best seen in Figure 2), comprising *inter alia*:

- a vacuum assisted biopsy device (the vacuum assisted retrieval instrument/ retrieval mechanism/ biopsy forcep inserted through channel 26 as positively recited in

column 1 lines 9-21, column 2 lines 41-46 and 50-52, and column 4 lines 1-4) (as best seen in Figure 2);

- a first fluid source (the source of atmospheric fluidic air vacuumed into pneumatic bulb 22) (as best seen on the right-most side of Figure 6) (column 2 line 53 – column 3 line 37);
- a second fluid source (the suitable fluid in syringe 33) (as best seen in Figures 2 and 4) (column 2 line 53 – column 3 line 37); and
- a fluid connector (18) (as best seen in Figures 2-6) (column 2 line 53 – column 3 line 37) configured to provide the first and second fluid sources in communication with the biopsy device (as best seen in Figures 2-6) (column 2 line 53 – column 3 line 37),
- the fluid connector, comprising *inter alia*:
    - a body member (18) (as best seen in Figures 2-6) (column 2 line 53 – column 3 line 37) having a first input port (the right-most terminus of the connector as best seen in Figure 6) (column 2 line 53 – column 3 line 37) in fluid communication with the first fluid source (column 2 line 53 – column 3 line 37),
    - a first check valve (28) (as best seen in Figure 6) (column 2 line 53 – column 3 line 37) in fluid communication with the first input port (as best seen in Figure 6) (column 2 line 53 – column 3 line 37),

- the first input port adapted to mate (e.g. associated suitably in fluid communication) with the first check valve (as best seen in Figure 6) (column 2 line 53 – column 3 line 37),
- a second input port (syringe socket 34) (as best seen in Figure 4) (column 2 line 53 – column 3 line 37) in fluid communication with the second fluid source (as best seen in Figure 6) (column 2 line 53 – column 3 line 37),
- a second check valve (32) (as best seen in Figures 4-6) (column 2 line 53 – column 3 line 37) in fluid communication with the second input port (as best seen in Figures 4-6) (column 2 line 53 – column 3 line 37),
- the second input port adapted to mate (e.g. associated suitably in fluid communication) with the second check valve (as best seen in Figures 4-6) (column 2 line 53 – column 3 line 37), and
- an outlet port (the distal outlet of combined insufflation-irrigation channel 40) (column 2 line 53 – column 3 line 37) (as best seen in Figures 2-7) in fluid communication with the vacuum assisted biopsy device (column 2 line 53 – column 3 line 37) (the fluid communication between the outlet port and vacuum assisted biopsy device as best seen in Figure 7),
- wherein the first check valve is selectively opened when a vacuum is created in the fluid connector (column 3 lines 4-8).

14. For independent claim 14, Siegmund discloses a fluid connector (18) (as best seen in Figures 2-6) (column 2 line 53 – column 3 line 37) for a biopsy system (the

vacuum assisted retrieval instrument/ retrieval mechanism/ biopsy forcep inserted through channel 26 as positively recited in column 1 lines 9-21, column 2 lines 41-46 and 50-52, and column 4 lines 1-4) (as best seen in Figure 2) including a vacuum assisted biopsy device (the vacuum assisted retrieval instrument/ retrieval mechanism/ biopsy forcep inserted through channel 26 as positively recited in column 1 lines 9-21, column 2 lines 41-46 and 50-52, and column 4 lines 1-4) (as best seen in Figure 2), a first fluid source (the source of atmospheric fluidic air vacuumed into pneumatic bulb 22) (as best seen on the right-most side of Figure 6) (column 2 line 53 – column 3 line 37), and a second fluid source (the suitable fluid in syringe 33) (as best seen in Figures 2 and 4) (column 2 line 53 – column 3 line 37), the fluid connector comprising *inter alia*:

- a body member (18) (as best seen in Figures 2-6) (column 2 line 53 – column 3 line 37) having a first input port (the right-most terminus of the connector as best seen in Figure 6) (column 2 line 53 – column 3 line 37);
- a second input port (syringe socket 34) (as best seen in Figure 4) (column 2 line 53 – column 3 line 37); and
- an output port (the distal outlet of combined insufflation-irrigation channel 40) (column 2 line 53 – column 3 line 37) (as best seen in Figures 2-7),
- wherein the first input port includes a first check valve (28) (as best seen in Figure 6) (column 2 line 53 – column 3 line 37) in fluid communication with the first fluid source (as best seen in Figure 6) (column 2 line 53 – column 3 line 37),

- wherein the first input port is adapted to mate (e.g. associated suitably in fluid communication) with the first check valve (as best seen in Figure 6) (column 2 line 53 – column 3 line 37),
- wherein the second input port includes a second check (32) (as best seen in Figures 4-6) (column 2 line 53 – column 3 line 37) valve in fluid communication with the second fluid source (as best seen in Figures 4-6) (column 2 line 53 – column 3 line 37),
- wherein the second input port is adapted to mate (e.g. associated suitably in fluid communication) with the second check valve (as best seen in Figures 4-6) (column 2 line 53 – column 3 line 37),
- wherein the output port is provided in communication with the vacuum assisted biopsy device (column 2 line 53 – column 3 line 37) (the fluid communication between the outlet port and vacuum assisted biopsy device as best seen in Figure 7), and
- wherein the first check valve is selectively opened when a vacuum is created in the fluid connector (column 3 lines 4-8).

15. For claims 3 and 16, Siegmund discloses the biopsy system and fluid connector, wherein the second check valve includes a resiliently compressible valve member (the valve ball positively recited in column 2 lines 53-59) (as best seen in Figures 5-6).

16. For claims 4 and 17, Siegmund discloses the biopsy system and fluid connector, wherein the second check valve includes a valve seat (the valve spring that biased the

valve ball positively recited in column 2 lines 53-59) adapted to secure the valve member within the second check valve (as best seen in Figures 5-6).

17. For claims 6 and 19, Siegmund discloses the biopsy system and fluid connector, wherein the second fluid source includes a needleless syringe (syringe 33) (as best seen in Figures 2 and 4) (column 2 line 53 – column 3 line 37).

18. For claims 8 and 21, Siegmund discloses the biopsy system and fluid connector, wherein the first check valve exhibits a predetermined cracking pressure (column 3 lines 4-8), and wherein the cracking pressure is dictated by a change of pressure within at least a portion of the biopsy device (column 3 lines 4-8).

19. For claims 9 and 22, Siegmund discloses the biopsy system and fluid connector, wherein the cracking pressure is less than or equal to a pressure resulting from the vacuum created in the fluid connector by the vacuum assisted biopsy device (column 3 lines 4-8).

20. For claims 27 and 29, Siegmund discloses the biopsy system and fluid connector, wherein the body member further comprises a housing (the exterior of element 18) (as best seen in Figures 2-3), said housing, comprising *inter alia*: said first input port (as best seen in Figures 2-7); said second input port (as best seen in Figures 2-7); said outlet port (as best seen in Figures 2-7); and a fluid passageway (the internal fluid passageway as best seen in Figures 3-6) extending through said housing (as best seen in Figures 3-6) and in fluid communication with said first input port (as best seen in Figures 3-6), said second input port (as best seen in Figures 3-6), and said outlet port (as best seen in Figures 3-6).

21. For claims 28 and 30, Siegmund discloses the biopsy system and fluid connector, wherein the housing is a unitary member (as best seen in Figures 2-3).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

24. Claims 2 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund (US 4,598,698) in view of Clement (US 5,505,210).

25. For claims 2 and 15, Siegmund discloses the claimed invention except for expressly disclosing the first check valve includes a duckbill valve member. Even though Siegmund appears silent with respect to a duckbill valve member, Siegmund is expressly concerned with using a ball check valve and explicitly states other check valve structure may be used without departing from the scope of the invention (column

2 lines 53-59). Moreover, Applicant states in the specification that a duckbill-style valve is a well known check valve (paragraph 40)

26. For claims 2 and 15, Clement teaches a biopsy system (10) (as best seen in Figure 14) and a fluid connector (718) (as best seen in Figure 14), comprising *inter alia*: a first check valve (740) (as best seen in Figure 14) (column 12 lines 15-37 and column 14 lines 7-10) including a duckbill valve member (740) (as best seen in Figure 14) (column 12 lines 15-37 and column 14 lines 7-10) for selectively permitting or excluding fluid passage during a medical procedure.

27. Thus for claims 2 and 15, the claimed invention would have been obvious because the substitution of one known check valve for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Siegmund and Clement teach using check valves for fluid management during medical procedures, it would have been obvious to one skilled in the art at the time of the invention to substitute one check valve for the other to achieve the predictable results of increasing the efficacy of fluid management via valves in a fluid connector used with a biopsy system to simplify and save time in surgical procedures by providing well known alternate fluid management configurations.

28. Claims 5, 7, 12, 18, 20, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund (US 4,598,698) in view of Miller et al. (US 2002/0082519, hereinafter Miller).

29. For claims 5, 7, 18, and 20, Siegmund discloses the claimed invention except for expressly disclosing the first fluid source is a bag of isotonic solution and the second fluid source includes an anesthetic or a haemostatic agent. Even though Sigmund appears silent with respect to what the suitable fluid in the syringe is, Sigmund is expressly concerned with insufflating, irrigating, and vacuuming while removing biopsy samples. The Examiner notes isotonic solutions and anesthetics are well known irrigation fluids used during medical procedures.

30. For claims 5, 7, 18, and 20, Miller teaches a biopsy system and a fluid connector, comprising *inter alia*: a first fluid source is an isotonic solution (saline; paragraphs 141-144) delivered to the system via a hydraulic control system (15) and a second fluid source is an anesthetic (paragraph 90; “anesthetic”) delivered to the system via an irrigation fitting (145).

31. Thus for claims 5, 7, 18, and 20, all of the fluid delivery components are known in Siegmund and Miller. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the fluid delivery components as taught by Siegmund with the fluid delivery components as taught by Miller to achieve the predictable results of increasing the efficacy of a biopsy system having fluid management therewith to sufficiently perform irrigation during a medical biopsy procedure by configuring it to deliver anesthetics and/or saline.

32. For claims 12 and 25, Siegmund discloses the claimed invention except for expressly disclosing the vacuum created in the fluid connector by the vacuum assisted biopsy device is configured to draw a predetermined amount of fluid from the second fluid source through the output port and into the biopsy device when the second fluid source is connected thereto. Even though Siegmund appears silent with respect to the use of vacuum to draw predetermined amounts of fluid, Sigmund is expressly concerned with using the fluid connector to aid in delivery of the suitable fluid in the syringe (column 3 lines 10-23).

33. For claims 12 and 25, For claims 5, 7, 18, and 20, Miller teaches a biopsy system and a fluid connector, comprising *inter alia*: a vacuum (paragraphs 141-143, especially 143) created in a fluid connector (192) (paragraphs 141-143, especially 143) by a vacuum assisted biopsy device (300) (paragraphs 141-143, especially 143) is configured to draw a predetermined amount of fluid from a second fluid source (400) (paragraphs 141-143, especially 143) through an output port (the output of pinch valve 402) (paragraphs 141-143, especially 143) and into the biopsy device when the second fluid source is connected thereto (paragraphs 141-143, especially 143).

34. Thus for claims 12 and 25, all of the fluid management components are known in Siegmund and Miller. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the fluid management components as taught by Siegmund with the fluid management components as taught by Miller to achieve the predictable results of increasing the efficacy of a biopsy system having fluid

management therewith to sufficiently perform fluidic irrigation during a medical biopsy procedure by configuring it to automatically deliver saline via a valved operation.

35. Claims 10 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund (US 4,598,698) in view of Moore (US 2,866,457).

36. For claims 10 and 23, Siegmund discloses the claimed invention except for expressly disclosing the cracking pressure is greater than a pressure resulting from the vacuum created in the fluid connector by the vacuum assisted biopsy device when the second check valve is open. Even though Siegmund appears silent with respect to the cracking pressure of the first check valve being greater when the second check valve is open, Sigmund is expressly concerned with configuring the cracking pressure of the check valves to appropriately effect fluid management (column 2 lin3 53 - column 3 line 37).

37. For claims 10 and 23, Moore teaches a medical device having fluidic administration management comprising check valves (column 1 line 56 – column 2 line 44) therein and that it is desirable to keep the two fluid sources isolated and that fluid can not pass the check valves in a wrong direction (column 2, lines 15-18). Thus, the cracking pressure is greater than a vacuum created in the fluid connector when the second check valve is open in order to prevent backflow of one fluid into the other fluid source.

38. Thus for claims 10 and 23, all of the fluid management components are known in Siegmund and Moore. The only difference is the combination of the fluid management

component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the fluid management components as taught by Siegmund with the fluid management components as taught by Moore to achieve the predictable results of increasing the efficacy of a biopsy system having fluid management therewith to sufficiently perform fluidic irrigation and/or administration during a medical procedure by configuring it to automatically prevent fluid flow in a wrong direction via suitable check valve(s).

39. Claims 11, 13, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund (US 4,598,698) in view of Turturro et al. (US 6,331,165 B1, hereinafter Turturro).

40. For claims 11, 13, 24, and 26, Siegmund discloses the claimed invention except for expressly disclosing the second check valve includes a female luer fitting, the second fluid source includes a male luer fitting adapted to mate with the female luer fitting, and the first and second check valves include a female luer fitting. Siegmund appears silent with respect to the coupling and/or fitting of the check valves to the fluid sources; however, it is well known in the art to provide couplings and fittings between valves and fluid sources in fluidic communication. Moreover, male and female luer fittings are well known in the art of fluidic connections between valves and fluid sources and are routinely used.

41. For claims 11, 13, 24, and 26, Turturro teaches a biopsy system and a fluid connector, comprising *inter alia*: providing male and female luer fittings between

irrigation fluid sources and valves (column 18 line 16 – column 19 line 15) (as best seen in Figure 28) for the purpose of providing quick and easy connection and disconnection.

42. Thus for claims 11, 13, 24, and 26, all of the fluid management components are known in Siegmund and Turturro. The only difference is the combination of the fluid management component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the fluid management components as taught by Siegmund with the fluid management components as taught by Turturro to achieve the predictable results of increasing the efficacy of a biopsy system having fluid management therewith to sufficiently perform fluidic irrigation and/or administration during a medical procedure by configuring it with luer type connection fittings/couplings to establish and ensure fluid is contained in the system and to provide a means for quickly and easily connecting and disconnecting the fluidic components.

Response to Arguments

43. Applicant's arguments with respect to claims 1-30 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

44. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am

to 5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

45. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736